Saul Ewing LLP

Charles M. Lizza
Phone: (973) 286-6715
Fax: (973) 286-6815
clizza@saul.com
www.saul.com

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VIA ECF

The Honorable Katharine S. Hayden
United States District Judge
District of New Jersey
U.S.P.O. & Courthouse Bldg., Room 311
Newark, New Jersey 07101-0999

Re: *EKR Therapeutics, Inc. v. Sun Pharmaceutical Industries Ltd.*
Civil Action No. 07-1788 (KSH)(PS)

Dear Judge Hayden:

This firm, together with Quinn Emanuel Urquhart Oliver & Hedges, represents Plaintiff EKR Therapeutics, Inc. ("EKR") in the above-captioned action. We submit this letter to address a limited number of specific issues raised by Defendant Sun Pharmaceutical Industries Ltd.'s Brief in Opposition To EKR's Application For A Temporary Restraining Order ("Sun Opp.")

Irreparable Harm: Sun's arguments against irreparable harmed ignore the facts specific to EKR that are set forth in the DeSimone Declaration. When the facts of this case are considered, it is clear that Sun's heavy reliance on *Novartis Corp. v. Teva Pharm. USA, Inc.*, 2007 WL 1695689 (D.N.J. 2007) is misplaced. *See* Sun Opp. at 23. Unlike EKR, Novartis is not a relatively small company, and Novartis did not rely on the product line covered by the patent in that case for the majority of its revenue. Instead, as Teva's expert pointed out in that case, Novartis's revenues for the previous year had been more than $36 billion, and its gross profits were over $26 billion. *See* 2007 WL 1695689 at *28. Moreover, in *Novartis*, Teva's expert conceded that Novartis's arguments concerning irreparable harm "'might make sense in the context of a small firm for which the patented product represents a large portion of its revenues and profits….'" *Id.* This case presents precisely that situation – EKR is a relatively small company, and the Cardene® I.V. products account for a substantial portion of EKR's revenue. Here, the damage to EKR's business upon Sun's premature launch would be irreparable.

Likelihood of Success on the Merits: Although there are numerous flaws and omissions in Sun's arguments on the merits, EKR will focus on just a few at this time. To begin, Sun completely ignores the fact that its product has already been found to infringe the '405 patent.

In addition, Sun's anticipation argument based on EP '475 is fatally flawed on its face. Sun admits that EP '475 "does not explicitly disclose a pH range at about 3.0 to 4.5, as disclosed in Claims 1 and 3 of the '405 patent." *See* Sun Opp. at 17. Sun does not even argue that the claimed range is inherently anticipated, but instead asserts that it would have been obvious. Because EP '475 does not disclose, either expressly or inherently, a pH range at about 3.0 to 4.5, it cannot anticipate the '405 patent claims. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1375 (Fed. Cir. 2007) ("A determination that a patent is invalid as being anticipated under 35 U.S.C. § 102 requires a finding that 'each and every limitation is found either expressly or inherently in a single prior art reference.'") (citation omitted).

Moreover, Sun's obviousness arguments all rely on a piece of prior art, EP '705, that was before the examiner during prosecution of the '405 patent.

Balance of the Hardships: Sun does not cite a single case, and EKR is not aware of a case, in which the balance of harms tipped in favor of an adjudicated infringer that was seeking to launch its infringing product during the pendency of the litigation.

Although the balance favors EKR, Sun attempts to tip that balance by accusing EKR of delay. *See* Sun Opp. at 26-27. Sun is wrong, and Sun's reliance on *Novartis Corp.* is once again misplaced. In *Novartis*, the court noted that Novartis could have brought a preliminary injunction motion eight months earlier, when Teva received preliminary approval for its ANDA. *Novartis Corp.*, 2007 WL 1695689 at * 30. In this case, Sun has never received preliminary approval for its ANDA. In fact, it appeared that Sun would never receive preliminary approval for its ANDA. In *Novartis*, the court also noted that the request for preliminary relief was filed more than a month ***after*** the 30 month stay had expired. 2007 WL 1695689 at * 30. Here, EKR sought preliminary relief immediately upon expiration of the 30 month stay. Most telling, however, is the fact that, despite the court's criticism of Novartis's delays, and notwithstanding its doubts as to patentee's likelihood of success on the merits of infringement, the balancing of the hardships tipped in Novartis's favor in that case. *See Novartis Corp.*, 2007 WL 1695689 at *31. Like Novartis, EKR has a "great interest in enforcing the [patent-in-suit] throughout its remaining useful, and substantial income-earning, life" and the balance of hardships here is heavily in EKR's favor. *See id.*

The Public Interest: Sun argues that the statutory framework seeks to make low cost drugs available (Sun Opp. at 27), but ignores the fact that "it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical patents. Nor does the statutory framework encourage or excuse infringement of valid pharmaceutical patents." *See Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005).

In essence, Sun argues that EKR should be deprived of the last few months of its patent's term because EKR has already enjoyed years of exclusivity. Yet those years of undisturbed exclusivity are further indication that the '405 patent is valid and should be enforced until the end of its term. *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1359 (Fed.

Cir. 2001) (noting that support for a clear case of patent validity "might come from a long period of industry acquiescence in the patents' validity.")

Sufficient Bond: Sun argues that the amount of the security bond should be set on the "high side" because Sun is "poised to capture a share of the market. . . ." Sun Opp. at 29. But Sun will not be "poised to capture a share of the market" unless and until the FDA approves Sun's application. Accordingly, any bond should be nominal until such time as Sun has received final FDA approval and has come forward with competent evidence of the appropriate amount of bond at that time. *See Eisai Co., Ltd. v. Teva Pharma. USA, Inc.*, 2008 WL 1722098, at *12-13 (D.N.J. March 28, 2008) (requiring that the parties submit evidence concerning the appropriate amount of bond).

Respectfully yours,

Charles M. Lizza

cc: All counsel (via e-mail)